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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/818,168	03/27/2001	Michael A. Munoz	85864	1917

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EXAMINER

GOTTSCALK, MARTIN A

ART UNIT	PAPER NUMBER
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3626

DATE MAILED: 03/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/818,168	MUNOZ ET AL.	
	Examiner	Art Unit	
	Martin A. Gottschalk	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7,22,23 and 26-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7,22,23 and 26-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Notice to Applicant

1. This office action is responsive to the communication received on 10/24/05. Claims 1-7, 22-23, and 26-33 are pending. Claims 8-21 and 24-25 are cancelled. Claims 1-4, 7, and 22-23 are amended. Claims 29-33 are new.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 26-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims depend from claim 1 which claims a method, but the preamble of the claims themselves recite "The system of claim 1...". Correction is required. For the purpose of examination, the Examiner will consider the word "system" to read "method" in the cited claims.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 1-4, 6, 7, 22, 23, and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kobylevsky et al. (US Pat# 6,493,427, hereinafter Kobylevsky) and further in view of Goetz et al (US Pat# 6,421,650, hereinafter Goetz).

A. As per claim 1, Kobylevsky discloses a method of processing a prescription refill request via an interactive voice response system (Kobylevsky: abstract), the method comprising the steps of:

(a) providing access for a pharmacy to an interactive response system (Kobylevsky: col 2, lns 53-56; Fig. 1, note the arrows running between the Central Pharmacy System and the Pharmacy) for obtaining approval of a refill request from a physician (col 6, lns 30-35; col 7, lns 32-42);

(b) prompting the pharmacy for a pharmacy identification (Kobylevsky: Fig. 2, note the field marked "Pharmacy Name". The Examiner considers that pharmacy staff are among those who might be entering the name, and thus would be receiving the prompt.).

Kobylevsky fails to explicitly disclose the steps of

(c) prompting the pharmacy for a patient identification; and

(d) prompting the pharmacy for an NDC number of a medication corresponding to the prescription to be filled,

wherein at least one of the prompting steps includes audibly prompting the pharmacy.

However, these features are well known in the art as evidenced by the teachings of Goetz:

As per step (c), Goetz teaches

(c) prompting the pharmacy for a patient identification (Goetz: col 11, Ins 40-46.

The Examiner considers the required step where the pharmacist must verify

“...the authenticity of the prescription...” before being able to fill the prescription to be a form of prompting for patient identification); and

As per step (d) Goetz teaches a health care provider inputting an NDC number corresponding to the prescription to be filled to supply necessary information about the medication to the patient (Goetz: col 6, Ins 1-19), and the NDC number being used in pharmacist software to provide information about drug interaction (Goetz: col 12, Ins 51-53; Fig 44, item 206). It is logical that the pharmacist component would provide a prompt, such as a blank input field labeled “NDC”, as a guide for the user seeking to obtain interaction information for a particular drug or drugs.

As per at least one of the prompts being audible, audible alerts and prompts are well known in the personal electronics and computer arts, take for example Goetz: col 5, Ins 23-24. As a matter of design choice, the inventor could have included audible alerts in the pharmacist component as prompts for any circumstance desired.

It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate the teachings of Goetz within the method of Kobylevsky in order to provide patients easy access to complete medical information on a prescription (Goetz: col 1, Ins 64-67).

B. As per claim 2, Kobylevsky discloses the method of claim 1, further comprising the step of

providing an authorization for the requested refill (Kobylevsky: col 7, Ins 39-42; col 29, Ins 9-22;),

but fails to disclose

displaying both the NDC number and the name of the medication to a physician for providing an authorization for the requested refill.

However, this feature is well known in the art as evidenced by the teachings of Goetz.

Goetz teaches a health care provider inputting an NDC number corresponding to the prescription to be filled to supply necessary information about the medication to the patient (Goetz: col 6, Ins 1-19), and the NDC number being used in physician software to display information about drug interaction (Goetz: col 12, Ins 51-53; Fig 44, items 206 and 212). The drug name is displayed along with the interaction warning (Goetz: Fig 23) for the physician to provide authorization for the prescription (Fig. 24). It is logical that the physician component, merely as a matter of design choice, could also display

the NDC number, acquired from the database providing the information shown in Fig 44.

The motivation to combine the teachings of Goetz and Kobylevsky are the same as provided above for claim 1 and are incorporated herein.

C. As per claim 3, Kobylevsky discloses the method of claim 1, further comprising at least one of the steps of:

confirming the pharmacy identification (Kobylevsky: Fig. 2, note the field marked "Pharmacy Name"; col 25, Ins 36-39; the Examiner considers the step of entering the pharmacy's name into the computer after typing it into the provided data entry field be a form of confirming the pharmacy identification.);

confirming the patient identification (Kobylevsky: col 7, Ins 35-42. Note the prompting for "...patient full name and phone number...". The Examiner considers requiring these two separate pieces of information to be a form of confirming the patient identification); and

confirming the medication (Kobylevsky: col 25, 12-23. The Examiner considers entering the Rx number into the system followed by playback to the customer to be a form of confirming the medication.)

D. As per claim 4, Kobylevsky discloses the method of claim 1, further comprising at least one of the steps of:

prompting for the date the prescription was last filled (Kobylevsky: col 7, Ins 57-61. The Examiner being required to enter the Rx number to be a form of prompting for the date the prescription was last filled, since the Rx number will have this date associated with it.);

prompting for the identification of the original prescribing physician (Kobylevsky: col 7, Ins 35-42, reads on "...state their full name and phone number..."); and

prompting for the quantity of the medication (Kobylevsky: col 7, Ins 40-42, reads on "...all relevant information for the...refill authorization...". Also col 7, Ins 57-61. The Examiner being required to enter the Rx number to be a form of prompting for the quantity of the medication, since the Rx number will include the quantity.).

E. As per claim 6, Kobylevsky discloses the method of claim 1, further comprising the steps of:

creating a database entry for each prescription refill request (Kobylevsky: col 24, Ins 6-20 and 59-61).

However, Kobylevsky fails to explicitly disclose the method of claim 1, where the database entry for each prescription refill includes:

the NDC identification and a corresponding commercial or generic name of the medication corresponding to the NDC identification, whereby a physician or individual may consider and provide the refill authorization based on the commercial or generic name of the medication.

However, these features are well known in the art as evidenced by the teachings of Goetz.

Goetz teaches a relational database which includes drug names and their corresponding NDC numbers (Goetz: col 15, lns 32-37; Fig. 44, note in particular the fields labeled "Drug" and "NDC"). Fig. 44, item 212 in particular shows a step where a physician or individual might consider this information.

The motivation to combine the teachings of Goetz within the method of Kobylevsky are the same as provided for claim 1 and is incorporated herein.

F. As per claim 7, Kobylevsky discloses the method of claim 6, further comprising at least one of the steps of:

providing a physician or other user access to the database entry (Kobylevsky: col 29, lns 18-31);

prompting the physician or other user to enter comments (Kobylevsky: col 7, Ins 42-45);

prompting the physician or other user to indicate approval of the request (Kobylevsky: col 7, Ins 36-42, reads on "...prompted by the system to...<provide> refill authorization."); and

prompting the physician or other user to dispatch the indication of approval and corresponding comments, if any, to the requesting pharmacy (Same reasons as provided above for the rejection of the previous two "prompting..." steps.)

Kobylevsky fails to explicitly disclose the step of:

prompting the physician or other user for the confirmation that the requested prescription is compatible with other medications, if any, prescribed to the patient;

However, this step is well known in the art as evidenced by the teachings of Goetz.

Goetz teaches a system that checks a drug about to be prescribed for potential interactions with other drugs (which would include drugs already prescribed to the

patient), then prompts for confirmation whether or not to go ahead and prescribe the medication should potential interactions be discovered (Goetz: col 11, 29-39; Figs 23 and 24).

The motivation to combine the teachings of Goetz within the method of Kobylevsky are the same as provided for claim 1 and is incorporated herein.

G. As per claim 26, Kobylevsky fails to explicitly disclose the system of claim 1, wherein all three of the prompting steps includes audibly prompting the pharmacy.

However, this feature is well known in the art as evidenced by Goetz. As explained in the rejection for claim 1 above, audible alerts and prompts are well known in the personal electronics and computer arts, take for example Goetz: col 5, Ins 23-24. As a matter of design choice, the inventor could have included audible alerts in the pharmacist component as prompts for any circumstance desired.

The motivation to combine the teachings of Goetz and Kobylevsky are the same as provided above for claim 1 and are incorporated herein.

H. As per claim 27, Kobylevsky discloses the system of claim 1, further including the steps of responding to the prompting steps by using a keypad on a telecommunication device (Kobylevsky: col 6, Ins 44-47).

I. As per claim 28, Kobylevsky discloses the system of claim 1, further comprising the step of confirming at least one of the

pharmacy identification,

patient identification and

medication by:

providing an audible statement to the pharmacy, and

prompting for the pharmacy to indicate whether or not the statement is correct (Kobylevsky: col 6, lns 49-58. The Examiner considers "Order Status Verification" to be a form of confirmation of the medication, and further considers this to be an example of providing an audible statement to the pharmacy since the user is using the "Main Voice Menu" for this purpose. The Examiner further considers the user's inquiry about the status of the order to be a form of a prompt to the pharmacy to indicate whether or not the order is ready.).

J. As per claims 22 and 23, they are system claims which repeat the same limitations of claims 1 and 6, the corresponding method claims, as a collection of elements as opposed to a series of process steps. Since the teachings Kobylevsky and Goetz disclose the underlying process steps that constitute the methods of claims 1 and 6, it is respectfully submitted that they provide the underlying structural elements that perform the steps as well. As such, the limitations of claims 22 and 23 are rejected for the same reasons given above for claims 1 and 6.

7. Claims 29-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kobylevsky in view of Goetz, and further in view of Pilarczyk (US Pat# 4,766,542, hereinafter Pilarczyk).

A. As per claim 29, Kobylevsky discloses a method of processing a prescription refill request comprising the steps of:

(a) audibly prompting a pharmacy (Kobylevsky: col 6, Ins 49-52) to provide information related to the refill request (Kobylevsky: col 16, Ins 66-67; col 27, Ins 36-40; Figs 8 and 9, column field labeled "Status", i.e. after the pharmacy is prompted, it fills the prescription and provides the "Filled" information regarding the refill request to the system.);

(b) providing the information by using a keypad on a telecommunication device (Kobylevsky: col 16, Ins 34-42, i.e. the keyboard can be used to navigate and enter information.);

(c) confirming the information by providing the pharmacy with an audible statement (Kobylevsky: col 26, Ins 54-61. The Examiner points out that audible alerts are well known in the art as disclosed in the passage, and considers the cited "sound alert" to be a form of audible statement. Furthermore, the Examiner considers the cited change in color to be a form of confirmation that the prescription has been filled, and notes that the an artisan of ordinary skill could have included a sound along with the color change, merely as a matter of design choice.).

(d) answering whether or not the audible statement is correct by using a keypad (Kobylevsky: col 26, Ins 62-65. The Examiner considers moving the pointer to the next row using the keyboard to be a form of answering that a refill request has been filled, i.e. the user moves on to the next request.); and

Kobylevksy fails to disclose

(e) displaying the information to a physician required to approve or deny the refill request.

However, this feature is well known in the art as evidenced by the teachings of Goetz. Goetz discloses

(e) displaying the information to a physician required to approve or deny the refill request (Goetz: col 12, lns 32-50. The passage teaches a prescribing physician reviewing –i.e. displaying via the “physician’s component” - patient compliance with a treatment regimen approved by the physician.).

The motivation to combine the teachings of Goetz and Kobylevsky are the same as provided above for claim 1 and are incorporated herein.

B. As per claims 30-32, Kobylevsky and Goetz fail to disclose the method of claim 29, wherein

the information is the

(claim 30) pharmacy’s phone number,

(claim 31) a portion of a patient’s name

or

patient’s date of birth,

(claim 32) the NDC number of the medication requested for the refill request;

and

the audible statement is the

(claim 30) name of the pharmacy

(claim 31) patient's full name

(claim 32) name of the medication.

However, Kobylevsky and Goetz disclose methods and systems comprising databases which further comprise complete information regarding a pharmacy, a patient, and a prescription, such information comprising for example

a patient's name (Kobylevsky: col 20, Ins 31-32),

the name of the pharmacy (Kobylevsky: Fig 2, field labeled "Pharmacy Name"),

the name of the medication being prescribed (e.g. Goetz: Fig 21, i.e. "Canderill").

the NDC number of the medication requested for the refill request (Goetz: col 15, Ins 32-37),

Kobylevsky and Goetz collectively disclose performing the steps of the method of claim 29 as described above in the rejection of claim 29. What further remains to be

taught is the ability to access information in a database and convert it into an audible message, which Kobylevsky and Goetz fail to explicitly disclose.

However, this feature is well known in the art as evidence by the teachings of Pilarczyk. Pilarczyk teaches a method and system incorporating a speech synthesizer that takes as input prescription-related information (Pilarczyk: col 1, ln 67 to col 2, ln 2; Fig 1, item 18) so as to provide audible output regarding refill information (Pilarczyk: col 3, lns 56-67). Pilarczyk further teaches that commercially available speech synthesis systems are old and well known (Pilarczyk: col 4, ln 46 to col 5, ln 15), and describes in detail the operation of such a system (Pilarczyk: col 7, ln 40 to col 9, ln 68).

It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate the teachings of Pilarczyk with the collective teachings of Kobylevsky and Goetz with the motivation of providing greater assurance a patient obtains the full prescribed number of doses of a drug, encouraging greater patient compliance with a prescription regimen, and promoting increased return business to a pharmacy from a patient (Pilarczyk: col 1, lns 14-50).

C. As per claim 33, it recites the method of claim 29, wherein

both the NDC number and the name of the medication is displayed to the physician. It is rejected as per the reasons provided for the same limitation recited in claim 2 above.

8. The remaining claims were not amended and are thus rejected for the reasons provided in the first Office Action.

Response to Arguments

9. Applicant's arguments with respect to claims 1-4, 6, 7, 22, 23, and 26-33 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Martin A. Gottschalk whose telephone number is (571) 272-7030. The examiner can normally be reached on Mon - Fri 8:30 - 5.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (571) 272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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01/18/2006


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